Medical Device Design Verification Essentials

By Alec Alpert

At some point in the new medical device development, design verification must be performed to satisfy the applicable regulations and standards such as:

21 CFR 820.30 Design Controls

(f) Design verification. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

ISO 13485:2016

7.3.6 Design and development verification

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include methods, acceptance criteria and, as

appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs.

But regulations aside, we want to convince ourselves that the design meets product requirements and specifications.

Basically, design verification demonstrates that design outputs meet design inputs. In other words, functional inputs outlined in the product requirements/specifications are tested to demonstrate that the design performance meets the product's requirements.

When deciding what specific product requirement characteristics to verify, risks classifications derived from the risk analysis (Design FMEA or FTA) should be used as the criteria.

Like any other processes, design verification has a certain workflow that typically includes these key deliverables:

- Design Verification Master Plan (DVMP)
- Design Verification Protocol(s)
- Data Collection - Execution of Design Verification Protocol(s)
- Design Verification Report(s)

Let's look at each deliverable in more detail.

Design Verification Master Plan

The Design Verification Master Plan communicates and documents consensus regarding the scope of the verification activities. Inputs to the DVMP are the product requirements and the risk analysis. The DVMP should include the following essentials:

- Purpose
- Scope
- Reference documents
- Linking of the design characteristics to specific verification protocols, including limit testing
- Definition of each product specification requirement
- A matrix showing how each design input requirement will be addressed, including the associated risk analysis values
- Estimated sample size requirements for each protocol
- Specified traceability methodology for design verification builds
- Defined equipment installation and control methodology

Design Verification Protocol

The Design Verification Protocol(s) documents how product specifications will be tested as required by the DVMP. A Design Verification Protocol typically includes the following:

- Purpose
- Scope
- Acceptance criteria per product requirements
- Sample size and justification of sample size
- Reference to the statistical techniques to be applied to the sample data for acceptance assessment
- Definition of test or inspection methods to be used. Test and inspection methods must be assessed for suitability by associating them with Test Method Validation and Inspection Method Validation.
- Sequence of test completion order to efficiently use samples and resources
- Packaging and labeling configurations
- Environmental conditioning (temperature, humidity, flush, soaking, bending, etc.)

Design Verification Sample Sizes

- Sample sizes should be determined based on risk classification from FMEA, FTA or Hazard Analysis, and the required confidence and reliability for variable and attribute data.
- Alternative sample sizes may be used if appropriately defined and justified in the applicable protocol.
- ISO, ASTM, or other international standards that test material may be used if they support an alternate sample size when the rationale relevant to how the sample effectively meets the standard is defined.

Limit Testing

Limit testing should be included in the design verification testing, which is testing near or at the tolerance extremes, especially of the specifications associated with the Design FMEA's high- or very high-risk classification. Specifications requiring limit testing should be listed in the Design Verification Master Plan, protocol(s), and report(s) with rationale that supports the limit testing chosen as well as rationale for excluded specifications.

Limit Testing Essential Points

- Stack-up analysis of worst-case tolerances should include a review of the impact of building the design at multiple design component limits, for instance, mating a shaft's largest inner diameter and smallest outer diameter.
- Stacked limit condition testing should be considered when a process capability study indicates that the stacked condition may routinely happen in manufacturing.
- When drafting the Limit Testing Protocol, it is prudent to review the Product Requirements and associated component and assembly specification tolerances with the Risk Priority Number (RPN) and severity levels of the requirement.

Limit Testing Sample Sizes

A company's procedures should provide guidelines for determining limit testing sample sizes and be based on:

- Confidence level
- Risk classification
- Reliability

Limit test samples should be manufactured per documentation that clearly describes the deliberate modifications during the sample manufacturing. Build records verifying dimensions should be recorded in the Design Verification Report.

Design Verification Report

The Design Verification Report should be prepared upon completion of the Design Verification Plan and its associated Design Verification Protocol(s) to summarize and discuss the design verification results. The report should include identification of the design, product performance with respect to the acceptance criteria, identification of the test methods used to perform testing, testing dates, and the names of personnel who performed the verification testing.

About the Author

Alec Alpert is a Quality Engineer and Consultant with an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities. He has helped to improve product quality and compliance at the leading medical device companies in applications ranging from linear accelerators, anesthesia systems, and implantable orthopedic devices to electronic imaging systems, infectious disease diagnostic systems, and electrosurgical generators. Alec is the owner of Alpert Engineering, LLC, an engineering consulting company that provides services to medical device companies. Alec is also the owner of www.alecalpert.com, where he publishes articles and white papers with practical advice on medical device technology, quality assurance, and compliance.